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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,043	06/15/2005	Anil Kishen	1304.P004US/LYH/ay	8341

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EXAMINER	
HOBBS, MICHAEL L	

ART UNIT	PAPER NUMBER
1797	

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02/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,043	KISHEN ET AL.	
	Examiner	Art Unit	
	MICHAEL HOBBS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-24* is/are pending in the application.

4a) Of the above claim(s) *13 and 20-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-12 and 14-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/06/2010 has been entered.

Election/Restrictions

2. Claims 13 and 20-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/29/2008.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Interpretation

4. Applicant has argued that the prior art of record does not include the “precursor” of the instant application. While the applicant may be their on lexicographer, a specific

definition defining the claimed precursor in such a way that precludes the "precursor" of the prior art of record is not present. As it stands, the "precursor" is defined in such a away that any chemical or molecule that can interact with a microorganism can be used within the coating of the biosensor and as such, the "precursor" of the applied art still reads on this limitation.

Claim Objections

5. Claim 12 is objected to because of the following informalities: claim 12 is dependent upon claim 12. For purposes of examination, the claim is being interpreted as being dependent on claim 11. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 5-7, 9-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Cramp et al. (US 4,560,248).

8. Cramp discloses a fiber optic sensor that for claim 1 includes the following limitations:

"for sensing and/or monitoring at least one property associated with transformation of a bio-chemical analyte by at least on microorganism": Cramp discloses that the sensor is used for detecting changes in chemical or physical parameters (col. 1 lines 5-7) and the biochemical analyte and microorganism are material worked upon by an apparatus (see also MPEP 2115). Furthermore, Cramp discloses that the chromophore used also includes enzymes which changes color in the presence of specific biological species (col. 2 lines 4-6) where the term biological species is being broadly interpreted to include microorganisms.

"at least one fiber optic member having at least one unclad portion"": The applied reference includes at least one optical fiber (fiber 1) with an unclad portion (Fig. 2).

"a coating applied to the at least on unclad portion": The inner homogenous portion (portion 16) is surrounded by an outer layer or coating (coating 18; col. 4 lines 22-23).

"by sol-gel *technique":* Regarding the method of forming the coating around the inner portion of the fiber, Applicant is reminded that process steps in an apparatus are not accorded patentable weight. "The patentability of a product does not depend on its method of production". If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)."

Furthermore, the processing steps do not structurally define the instant application over the prior art since the claimed processing steps do not impart a distinctive structural characteristic to the final product.

"a precursor of the biochemical analyte immobilized within the coating": Cramp discloses a chromophore (chol. 4 lines 22-24) that has been bonded to the glass with a silane coupling agent and is being interpreted as within the coating since the silane coupling agents allow the chromophore to be bonded within the interstices of the porous layer (col. 2 lines 59-61).

"said precursor is transformable by the at least one microorganism into the biochemical analyte": The precursor of the applied reference is fully capable of being "transformable" by the biological species or microorganism.

"wherein the precursor is mixed with a solution of the coating prior to applying the solution of the coating to the at least on unclad portion of the biochemical analyte": Applicant is reminded that process steps in an apparatus are not accorded patentable weight. "The patentability of a product does not depend on its method of production". If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)." Furthermore, the processing steps do not structurally define the instant application over the prior art since the claimed processing steps do not impart a distinctive structural characteristic to the final product.

"wherein the transformed biochemical analyte produces a spectroscopically detectable indicator of the at least on property, thereby detecting the at least one microorganism": As already discussed, the chromophore of the applied reference changes color in the presence of a specific biological species or microorganism.

9. With regards to claim 2, Cramp discloses that a portion of the fiber is a "declad portion" (Fig. 2).

10. For claim 5, the ends of the sensor of Cramp are connected to a light source and a detector or analysis means (col. 4 lines 14-18). For claims 6 and 7, the outer layer is a porous glass (layer 17; col. 4 lines 21-22) where this layer is being interpreted as a thin film (Fig. 2).

11. For claim 9, Cramp discloses a chromophore as the precursor and reads as a "other suitable compound".

12. The limitation of claim 10 is drawn to material worked upon by an apparatus and does not structurally define the instant application over the prior art.

13. Regarding claim 11, the claim differs from claim 1 with the inclusion of a light source and monitoring means. Cramp discloses the claimed limitations including the light source and monitoring means (a light source and a detector or analysis means (col. 4 lines 14-18)). The final limitation of claim 11 drawn to the transformation of the precursor is drawn to material worked upon by an apparatus and this limitation does not structurally define the instant application over the prior art.

14. The sensor of Cramp for claim 12 is fully capable of generating an evanescent wave form.

15. For claim 14, Cramp discloses identifying a biological species or microorganism as was discussed for claim 1. Cramp further discloses activating a light source at a first end of the sensor and monitoring the light with a detector (col. 4 lines 14-18). As the light interacts with chromophore on the unclad portion (col. 4 lines 14-18) and therefore, the detector monitors the light from the unclad portion of the sensor. The unclad portion of the fiber is coated with a precursor as was discussed in claim 1. The unclad portion is brought into contact with the environment for testing (col. 3 lines 32-34) which is being interpreted as "locating the sensor with its unclad section with the sample". Finally, the detector of the applied reference receives the light from the fiver (col. 4 lines 14-18) and detects the change in color of the chromophores when the chromphores are in the presence of a specific biological species or microorganism (col. 2 lines 4-6).

16. Therefore, Cramp meets the limitations of claims 1, 2, 5-7, 9-12 and 14.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cramp et al. (US 4,560,248).

21. Cramp differs from the instant claims requiring a plurality of portions and two or more separate fiber optic units. However, it would have been obvious for one of ordinary skill in the art to employ a plurality of unclad portions and fibers within Cramp in order to obtain the predictable result of running multiple tests in parallel. Furthermore, it is noted that duplication of parts (one unclad portion and one fiber versus a plurality of unclad portions and two or more fibers) with no presentation of a new or unexpected result over the prior art has no patentable significance, consult *In re Harza*, 247 F.2d 669, 124 USPQ 378 (CCPA 1960) and MPEP § 2144.04 VI (B).

22. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cramp et al. (US 4,560,248) in view of Soller (US 5,582,170).

23. Cramp differs from the instant claims regarding spectroscopically monitoring the output, conducting absorption analysis or operating a programmable device to receive the output.

24. Soller discloses fiber optic sensor for measuring nitric oxide that includes for claims 15 and 16 monitoring the adsorption of NOX into hemoglobin by using adsorption spectroscopy (col. 3 lines 54-56) and the analysis of the data is by adsorption analysis and identifying the peaks for identifying changes of the NO concentration (col. 5 lines 57-60). For claim 17, the data is sent to a computer (computer 9) that the light output and input of the system (col. 8 lines 48 and 49). Therefore, it would have been obvious to one of ordinary skill in the art to employ the technique of using adsorption spectroscopy as suggested by Soller with the testing steps of Cramp in order to obtain the predictable result of monitoring the target molecule bound to the fiber. The suggestion for doing so at the time would have been in order to provide an analysis of the signals received from the detector.

25. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cramp et al. (US 4,560,248) in view of Soller (US 5,582,170) as applied above and in further view of Carter et al. (US 4,608,344).

26. Cramp and Soller differ from the instant claim requiring a computer to identify the genus or species of a microorganism.

27. Carter discloses an optical wave guide that for claim 18, includes the step where an electronic unit (unit 62) receives data from a photomultiplier tube that has been amplified and provides a computation that provides the concentration of an unknown microorganism according to usual means which implies the use of an algorithm (col. 18 lines 35-38). Using this method would be obvious to one of ordinary skill in the art to employ the programmable device of Carter in order to identify the target microorganism of Cramp and Soller. The suggestion for doing so at the time would have been in order to have a microprocessor for computing the measured data and comparing this data with stored references (col. 18 lines 12-14).

28. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cramp et al. (US 4,560,248) in view of Soller (US 5,582,170) as applied above and in further views of Carter et al. (US 4,608,344) and Prober et al. (US 5,306,618).

29. Cramp, Soller and Carter differ from the instant claim regarding a programmable device that ascribes an index to the identified feature and provide an overall index for a sample.

30. Prober discloses a system for DNA sequencing that includes a computer (controller 52) that operates the overall system. For claim 19, Prober discloses for claim 19 that initializes data arrays (arrays R(I) & T(I)) and acquires the data points for each array from the detectors. This input is recorded on a data file, the index of each array is incremented, and a new data point is record. This is repeated based on a pre-determined number of data points that are to be acquired by the system (Fig. 4a).

However, Prober does not sum up these data points to generate a contamination value. This summation of the data points would be obvious to the skilled artisan since this is a standard mathematical operation and computer of Prober can be easily modified to perform this step. Therefore, it would be obvious to one of ordinary skill in the art to employ the indexing and data file suggested by Prober within the combined steps of Cramp, Soller and Carter in order to store the obtained features to a data file. The suggestion for performing this step at the time of the invention would have been in order to obtain the predictable result of being able to recall specific features based on where that feature has been indexed in the data file.

Response to Arguments

31. Applicant's arguments, see page 9 section iii, filed 01/06/2010, with respect to the rejection of claims 1-7 and 10-12 have been fully considered and are persuasive. The 35 USC 103(a) rejection of the claims has been withdrawn.

32. However, upon review of the previously applied references in light of applicant's amendment and remarks, a new ground of rejection is being presented based on a re-interpretation of the previously applied reference of Cramp.

33. The applicant has three common threads of arguments with regards to the applied reference of Cramp that appear on pages 8 and 10. The first is that the applied reference does not produce the coating for the optical fiber by the sol-gel technique. Second, the dye of Cramp is not the precursor of the instant application and third, that

the applied reference does not sense a microorganism. These arguments are not found persuasive. As stated in the above rejection, the process for making the coating by the sol-gel process is a process step in an apparatus and is not accorded patentable weight.

34. With regards to the claimed precursor, it is unclear, based on applicant's arguments and the disclosed specification, what applicant is trying to claim. The applied reference of Cramp discloses a chromophore which has been interpreted as the precursor of the instant application. Furthermore, it appears that any compound that interacts with a biological species, whether that compound is a dye, a sugar or an enzyme, is a precursor molecule. Therefore, the chromophore dye of Cramp meets this limitation.

35. Finally, with regards to the microorganism, this limitation within the apparatus claims constitutes material worked upon by an apparatus and therefore, does not structurally define the instant claim over the prior art. Also, Cramp discloses detecting a biological species which is being interpreted as a microorganism. Therefore, Cramp meets this limitation within the independent claim 1 and dependent claim 14.

36. Applicant's argument relating to claim 14 on pages 14-16 are now moot in light of the new interpretation of Cramp.

37. In response to applicant's argument on pages 18-20 with regard to the rejection of claims 15-19 that the references were impermissibly combined, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed

invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

38. Therefore, the claims stand rejected.

Conclusion

39. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M. H./
Examiner, Art Unit 1797